IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA

MARY A. CANTWELL, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. CIV-18-272-D
	)	
SCOTT M. DE LA GARZA, M.D., *et al.*,	)	
	)	
	)	
Defendants.	)	

ORDER

Before the Court is Defendant Ulrich Medical USA, Inc.'s Motion to Dismiss Plaintiffs' First Amended Complaint [Doc. No. 52], filed pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b).[1] Plaintiffs have filed a timely response [Doc. No. 55], and the movant has replied [Doc. No. 56]. Upon consideration, the Court rules on the Motion as follows.

Factual and Procedural Background

Plaintiff Mary Cantwell claims she suffered personal injuries as a result of medical malpractice by Defendant Scott De La Garza, M.D.[2] Dr. De La Garza is an orthopedic surgeon who implanted in Plaintiff's cervical spine a medical device designed,

[1] The Motion does not expressly move for dismissal under these rules but renews arguments raised in a prior motion [Doc. No. 28], which was granted by Order of November 13, 2018 [Doc. No. 45]. The instant Motion challenges whether Plaintiffs' amended pleading cures the prior deficiencies, and whether newly-asserted theories of recovery are sufficiently pleaded. The reader's familiarity with the November 13 Order is assumed.

[2] Plaintiff William Cantwell claims a loss of consortium based on injuries suffered by his wife. The parties agree Mr. Cantwell asserts derivative claims that depend on the sufficiency of Mrs. Cantwell's claims. *See* Def.'s Mot. at 14; Pls.' Resp. Br. at 7 n.1 Thus, the Court discusses only the primary claims, and references in this Order to "Plaintiff" mean Mrs. Cantwell.

manufactured, and marketed by Defendant Ulrich Medical USA, Inc. ("Ulrich"). Plaintiff alleges the device was not approved for use in the cervical spine by the United States Food and Drug Administration ("FDA") and the unapproved nature of the use, together with an unspecified financial relationship between Defendants and risks posed by the unapproved use, were not disclosed to her. Plaintiff reasserts in the Amended Complaint [Doc. No. 46] common law tort theories of recovery against Ulrich that were not sufficiently pleaded in her original complaint – fraudulent concealment or constructive fraud, and negligence per se. *See* 11/13/18 Order [Doc. No. 45] (hereafter "Order") at 6-7, 9-11. She adds two new theories of Ulrich's liability – lack of informed consent and breach of an implied warranty. Because the Court's prior Order states the applicable standards of decision, the Court proceeds directly to the merits of Ulrich's renewed Motion.

Discussion

1. Constructive Fraud

Plaintiff argues in general terms that the Amended Complaint adequately states a constructive fraud claim because Ulrich has sufficient notice of the claim, citing "bullet points" in Ulrich's brief summarizing the factual allegations on which the fraud claim is based. *See* Pls.' Resp. Br. at 8; Mot. Dismiss at 4-5. Plaintiff contends the alleged facts that Ulrich's medical device was implanted "for an undisclosed, experimental, off-label purpose by Dr. De La Garza acting in concert with Ulrich for the financial gain of each of them" and that "[a]n employee of Ulrich was present for the surgery" are sufficient to satisfy the specificity requirement of Rule 9(b). *See* Pls.' Resp. Br. at 8.

For the reasons previously stated in the November 13 Order, the Court disagrees with Plaintiff's position and finds that she has failed to cure the deficiencies in her fraud claim. Plaintiff "do[es] not identify any facts that would establish Ulrich owed Mrs. Cantwell a duty of disclosure or withheld information from her." *See* Order at 7. Nor does Plaintiff explain how alleged "collusion between the parties" (Pls.' Resp. Br. at 7) could satisfy the requirement of showing Ulrich's involvement in fraudulent activity.[3] Therefore, the Court finds that Plaintiff has failed to state a fraud claim against Ulrich.

2. Negligence Per Se

The deficiency previously found in Plaintiff's pleading regarding negligence per se was the failure to identify "the statute or regulation allegedly violated, and thus the duty allegedly breached, by the defendant's conduct." *See* Order at 10. The Court rejected Plaintiff's position that she "need not plead the violation of a particular statute or regulation to state a claim of negligence per se." *Id.* Following the amendment of her pleading, Plaintiff's argument to show that the Amended Complaint sufficiently states a negligence per se claim consists of a single sentence in her brief: "The paragraphs of the Amended Complaint (§§ 24-38) are very clear with respect to the protection provided to a consumer of a medical device and the parallel state law enactments applicable to this cause of action." *See* Pls.' Resp. Br. at 12.

An examination of the Amended Complaint reveals that, like the original pleading, Plaintiff refers generally to federal statutes requiring FDA approval of new medical

[3] The Court previously found that Plaintiffs failed to plead a plausible claim of conspiracy to commit fraud. *See* Order at 7-8.

devices, citing "[t]he Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*., via the Medical Devices Amendments of 1976 (MDA). 21 U.S.C. § 360c *et seq*." *See* Am. Compl., ¶ 24. Plaintiff adds citations to "parallel" statues in Article 14 of the Oklahoma Public Health Code, Okla. Stat. tit. 63, § 1-1401 *et seq*., and identifies specifically "63 O.S. § 1-1402(a)-(d), 63 O.S. § 1-1408, and 63 O.S. § 1-1409." *See* Am. Compl., ¶ 25. She also adds allegations that Ulrich designed its device "for use in cervical spines despite Ulrich's representations to the FDA during the premarket approval process pursuant to 21 U.S.C. § 360e," and marketed the device "for cervical indications, despite the labeling of the product and despite their [sic] contrary representations to the FDA in the premarket approval process, all in violation of 21 U.S.C. § 331 and parallel state laws, statutes and regulations." *See* Am. Compl., ¶¶ 26, 29. Regarding Ulrich's conduct in relation to these statutes, Plaintiff alleges only that "Ulrich's violations during FDA's premarket approval process and subsequent misrepresentation of its product in advertisements and to its patients constitutes [sic] violations of the abovementioned Federal and State laws, regulations and statutes." *Id*. ¶ 32.

Although Plaintiff has now included in the Amended Complaint citations to federal and state statutes that allegedly were violated, the Court finds that Plaintiff has failed to cure the deficiency in her pleading. The Court previously ruled that a claim of negligence per se, particularly in the context of federal regulation of medical devices, requires "the identification of a particular statute or regulation that provides the duty allegedly violated" so Ulrich receives sufficient notice of the conduct at issue to permit the assertion of the federal preemption defense provided by the FDCA, if appropriate. *See* Order at 10-11.

The federal statues cited in the Amended Complaint encompass multiple subject areas and broad categories of conduct (21 U.S.C. § 331) and mandate the process for premarket approval of certain medical devices (21 U.S.C. § 360e).[4] Plaintiff's factual allegations seem to focus on Ulrich's conduct in the FDA approval process, and she argues in her brief that "Ulrich manipulated the FDA's preapproval process." *See* Pls.' Resp. Br. at 13. But she disclaims any intention of bringing a "fraud on the FDA claim." *Id*.

Upon consideration of Plaintiff's arguments, the Court is left to wonder what duty of care established by any statute or regulation was allegedly breached by the conduct of which Plaintiff complains, namely, Ulrich's designing and marketing its device for an off-label use. The statutory citations added to the Amended Complaint provide no useful assistance. Further, Plaintiff expressly argues that she is not "attempt[ing] to enforce any FDA regulation" and "federal law does not supply any elements of the claim." *Id*. at 14. Under these circumstances, the Court finds that Plaintiff has failed to state a plausible claim of negligence per se.

3. Lack of Informed Consent

Plaintiff makes no effective response to Ulrich's assertion that it had no duty to obtain her informed consent to the procedure and did not breach any such duty. She argues that "[t]he combined actions of Ulrich and Dr. De La Garza resulted in Mrs. Cantwell['s] uninformed consent to the improper use of the Ulrich device" and explains that the claim

[4] Plaintiff cites state statutes that prohibit generally the manufacture and sale of adulterated or misbranded drugs and devices, and false advertising. *See* Okla. Stat. tit. 63, §§ 1-1402(a)-(d) 1-1408, 1-1409.

against Ulrich is based on the "conspiratorial nature of the relationship between Dr. De La Garza and Ulrich." *See* Pls.' Resp. Br. at 11. Plaintiff cites no legal authority for the existence of such a combined duty; the Court has previously found that Plaintiffs' have failed to plead a civil conspiracy claim. *See* Order at 7-8. Therefore, the Court finds that Plaintiff's claim against Ulrich based on an alleged lack of informed consent fails as a matter of law.

4. Breach of Implied Warranty

Plaintiff has added to the Amended Complaint allegations that "[p]rior to the surgical procedure, Ulrich . . . impliedly warranted to Plaintiffs that the [implanted device] was fit for the use for which it was intended" and that unspecified "actions" constitute "a breach of implied warranty, including but not limited to the warranty of implied fitness." *See* Am. Compl. ¶¶ 44, 45. Ulrich asserts that these conclusory allegations fail to identify what warranty was made, and fail to state a plausible breach of warranty claim. Ulrich also asserts that Plaintiff's only remedy for a breach of warranty under Oklahoma law is provided by the Uniform Commercial Code (UCC), but the surgical procedure at issue did not constitute a sale of goods and so was not governed by the UCC. *See* Def.'s Mot. at 7.

Plaintiff responds, without any citation of legal authority, that the UCC should apply where "the implantation of the device was a critical component of the surgery" and "that the 'labor or service' required to install, implant or replace any manufactured part should [not] outweigh responsibility for the sale of the device or part." *See* Pls.' Resp. Br. at 10. Regarding the nature of the warranty allegedly given by Ulrich, Plaintiff refers to "the warranty of implied fitness for use and fitness for purpose." *Id*. She also argues that "the

device installed in Mrs. Cantwell was not fit for the purposes of the surgery because the device failed to comply with the numerous federal statutes, regulations, and laws specifically cited in the complaint." *Id*.

Setting aside whether the UCC applies to an alleged sale of Ulrich's device to Plaintiff, Oklahoma law is clear that to prove a breach of warranty claim, Plaintiff must show: (1) "the existence of the warranty;" (2) "the warranty was broken;" and (3) "the breach was the proximate cause of the loss sustained." *See Am. Fertilizer Specialists, Inc. v. Wood*, 635 P.2d 592, 595 (Okla. 1981) (footnote omitted) (citing U.C.C. § 2-314 cmt. 13). Although unclear from Plaintiff's argument, it appears that the implied warranty at issue is one of fitness for a particular purpose. *See id*. at 595 & n.8 (implied warranty of merchantability requires that goods operate for their ordinary purpose; implied warranty of fitness for a particular purpose "envisages a specific use by the buyer which is peculiar to the nature of his business") (quoting U.C.C. § 2-315 cmt. 2); *see* Okla. Stat. tit. 12A, §§ 2-314(2)(c); 2-315.

Upon consideration, the Court finds that Plaintiff fails to allege sufficient facts to establish the existence of an implied warranty of fitness for a particular purpose with respect to a sale of Ulrich's device to Plaintiff. Thus, the Amended Complaint necessarily fails to show that the warranty was breached or that the breach was the proximate cause of Plaintiff's injury. Therefore, the Court finds that Plaintiff has failed to state a plausible breach of warranty claim.

Conclusion

For these reasons, the Court finds that Plaintiffs have failed to state any claim against Ulrich on which relief can be granted.[5] Further, because Plaintiffs indicate that they wish to stand on the Amended Complaint, the Court finds that further amendment of Plaintiffs' pleading would be futile and should not be permitted.[6]

Supplemental Jurisdiction

This case was removed to federal court based on federal question jurisdiction under 28 U.S.C. § 1331 and issues arising under the FDCA. *See* Notice of Removal [Doc. No. 1], ¶ 3. Having determined that Plaintiffs do not assert a negligence claim based on a violation of the FDCA, the Court questions whether it should exercise supplemental jurisdiction over this case. Tenth Circuit law is clear "that if federal claims are dismissed before trial, leaving only issues of state law, the federal court should decline the exercise of jurisdiction by dismissing the case without prejudice" or, in a removed case, remanding the case to state court. *See Brooks v. Gaenzle*, 614 F.3d 1213, 1229-30 (10th Cir. 2010) (internal quotation omitted); *Bauchman v. West High Sch.*, 132 F.3d 542, 549-50 (10th Cir. 1997)

[5] As previously noted, the parties agree that if Mrs. Cantwell fails to state a claim, the Amended Complaint also fails to state a claim on which Mr. Cantwell can obtain relief. *See supra* note 1.

[6] Plaintiffs state they "object to defendant's request that Plaintiffs be required to submit a second Amended Complaint repleading any cause of action" and the case should "proceed to the discovery stage of the proceedings." *See* Pls.' Resp. Br. at 7 n.1. But the federal pleading standard of Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). Also, a district court does not err by failing to authorize a plaintiff to amend a deficient complaint if the plaintiff fails to move for leave to amend. *See Garman v. Campbell Cty. Sch. Dist. No. 1*, 630 F.3d 977, 986 (10th Cir. 2010); *Burnett v. Mortg. Elec. Registration Sys., Inc.*, 706 F.3d 1231, 1238 n.4 (10th Cir. 2013).

(dismissal); *Roe v. Cheyenne Mountain Conference Resort, Inc*., 124 F.3d 1221, 1237 (10th Cir. 1997) (remand); *see also United States v. Botefuhr*, 309 F.3d 1263, 1273-74 (10th Cir. 2002); 28 U.S.C. § 1367(c)(3).

IT IS THEREFORE ORDERED that Defendant Ulrich Medical USA, Inc.'s Motion to Dismiss Plaintiffs' Amended Complaint [Doc. No. 52] is GRANTED. Plaintiffs' action against Defendant Ulrich Medical USA, Inc. is dismissed with prejudice.

IT IS FURTHER ORDERED that the remaining parties shall show cause within 14 days from the date of this Order why the case should not be remanded to the District Court of Oklahoma County, Oklahoma.

IT IS SO ORDERED this 17th day of May, 2019.

TIMOTHY D. DEGIUSTI
UNITED STATES DISTRICT JUDGE